510(k) Summary

Submission Information

Name and Address of the Sponsor: Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401-1677

Contact Person: Terry Sheridan Powell

Date of Summary Preparation: January 5, 2000

Device Identification

Proprietary Name: Duracon Symmetric Metal-Backed Patellar Component

Common Name: Artificial Knee Component

Classification Name and Reference: 888.3560: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.

Predicate Device Identification

The substantial equivalence of the subject devices is based on a comparison of the device to the following predicate components:

1) Duracon Conversion Metal-Backed Patella Components: K972752

2) Duracon Metal-Backed (non-modular) Patella Components: K923573

3) Duracon All Polyethylene Patella Components: K910235

Intended Use

The subject devices are single use components, intended for cemented use only. They are intended for use in conjunction with legally marketed Duracon femoral components as part of cemented total knee replacement surgery.

Indications:

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis.
- Rheumatoid arthritis.
- Correction of functional deformity.
- Revision procedures where other treatments have failed.
- Post-traumatic loss of knee joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy.
- Irreparable fracture of the knee.

Device Description

The subject Duracon Symmetric Metal-Backed Patellar Component is symmetric, metal-backed, non-modular, and available in standard and Duration stabilized polyethylene. The device features a three-pegged design for fixation to the host patella. It features a diameter of 33mm, and a polyethylene bearing thickness of 9mm. The plastic-to-metal assembly method is the same one featured on the predicate Duracon Metal-backed Patellar Components.

Statement of Technological Comparison

Materials

The materials for the subject devices are identical to those of predicate devices #1 and #2.

Indications for Use

The indications for use of the subject and predicate devices are the same.

Design

The design of the subject device is a blend of predicate devices #2 and #3. The subject device features the metal-backed aspect, and the same locking mechanism as predicate device #2, but the symmetric bearing surface of predicate device #3.

Performance Data

The peak axial disassembly force of four samples was measured. The average peak disassembly was higher than the average peak disassembly force measured for the predicate Duracon Conversion (modular) Metal-Backed Patella.

The subject components were tested under load conditions corresponding to stair climbing and chair rising activities. All components successfully withstood the test without wearing through the UHMWPE and without dissociating the UHMWPE from the metal backing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 10 2000

Ms. Terry Sheridan Powell
Regulatory Affairs Department
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K000091
Trade Name: Duracon Symmetric Metal-Backed Patellar Component
Regulatory Class: II
Product Code: JWH
Dated: January 6, 2000
Received: January 13, 2000

Dear Ms.Powell:

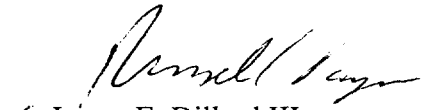
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000091

Device Name: Duracon Symmetric Metal-Backed Patellar Component

Indications For Use:

The subject devices are single use components, intended for cemented use only. They are intended for use in conjunction with associated Duracon femoral components as part of cemented total knee replacement surgery. Indications for use, in keeping with those of other commercially-available, Class II total knee devices, are as follows:

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis.
- Rheumatoid arthritis.
- Correction of functional deformity.
- Revision procedures where other treatments have failed.
- Post-traumatic loss of knee joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy.
- Irreparable fracture of the knee.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000091